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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,315	06/08/2006	Antonius Arnoldus Christiaan Jacobs	1-2003.025 US	1596
31846 7590 04/28/2009 Intervet/Schering-Plough Animal Health PATENT DEPARTMENT PO BOX 318 29160 Intervet Lane MILLSBORO, DE 19966-0318			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			NOTIFICATION DATE 04/28/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/582,315	Applicant(s) JACOBS ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Preliminary Amendment, received 8 June 2006, is acknowledged. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 15 have been amended.
2. Claims 1-15 are pending and under consideration.

Specification

The disclosure is objected to because of the following informalities:

Page 1, line 24, please define "i.a."

Page 2, line 26, "remaining" should be "retaining".

Page 12, line 31, "figure 2A and B" should be "Figure 2A and B".

Page 16, line 17, "table 2" should be "Table 2".

Page 21, line 13, "table 6" should be "Table 6".

Appropriate correction is required.

Tables

3. Tables 5 and 6 are placed with the submitted Drawings and not with the body of the specification as are Tables 1-4. If Tables 5 and 6 are to remain with the submitted Drawings, then a Brief Description of each is to be included in the section "Legend to the Figures".
4. Table 5 is objected to because in line 1, "table 5" should be "Table 5".
5. Table 6 is objected to because in line 1, "table 6" should be "Table 6".

Sequence Identifier Requirement

6. M.P.E.P. §2422.03, paragraph 9 recites:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without

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repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

7. Table 1 contains sequences without the required sequence identifiers.
8. M.P.E.P. §2422.02, third paragraph, recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

Figure 2A is objected to because it contains sequences without the required sequence identifiers.

Figure 2B is objected to because it contains sequences without the required sequence identifiers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are drawn to a live "over-attenuated" *O. rhinotracheale* strain. The instant specification, page 4, lines 25-27, defines over-attenuated as: "An over-attenuated *Ornithobacterium rhinotracheale* bacterium is a bacterium that (contrary to an attenuated *Ornithobacterium rhinotracheale* strain) is not capable of inducing a protective immune response to *Ornithobacterium rhinotracheale* in primed animals." In addition, the specification, page 5, lines 8-11 recites: "The nature of the mutation(s) leading to the over-attenuated behavior is not critical. Many attenuating mutations known in the art are suitable. Suitable *Ornithobacterium rhinotracheale* mutations are e.g. the classical PurD-, REcA- and Aro-mutations, known in the art for many bacterial species. Also, many temperature-sensitive mutants are suitable."

Lopes et al (*Avian Diseases*, 46:177-185, 2002) teach a temperature-sensitive mutant of *Ornithobacterium rhinotracheale* used as a vaccine to induce a protective immune response in turkeys to *Ornithobacterium rhinotracheale* (Abstract; section **Experiment 2**, page 179).

Thus, it is unclear what are the metes and bounds of "over-attenuated" as the teachings of Lopes et al appear to contradict the definition of the instant specification.

11. Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is drawn to an additional antigen "derived" from a virus or micro-organism. The instant specification does not define the term "derived".

Thus, it is unclear what are the metes and bounds of "derived" antigens.

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It is also unclear if the "virus or micro-organism pathogenic to poultry" includes or excludes the already encompassed live over-attenuated *O. rhinotracheale* stain and live attenuated poultry virus.

Claim 10 depends from claim 9, but does not clarify the issues.

Double Patenting

12. Applicants are advised that should claim 1 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 1 is a composition comprising only two listed components, live over-attenuated *O. rhinotracheale* and a live attenuated poultry virus.

Claim 14 is a kit (composition) comprising only two listed components, live over-attenuated *O. rhinotracheale* and a live attenuated poultry virus. The recitation of "optionally" comprising carriers places no patentable requirement on the claim.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 21, 2009